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10/584,968	06/30/2006	Aaron Kaplan	ANVIL.001BNP1	9697

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EXAMINER	
DORNBUSCH, DIANNE	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
10/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/584,968	KAPLAN ET AL.	
	Examiner	Art Unit	
	DIANNE DORNBUSCH	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-24,36-44,47 and 49-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-24,36-44,47 and 49-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/15/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. For examination purposes,"frond" is being interpreted as being any extension that is protruding from the proximal or distal portion of the stent. Additionally, the frond is a segment which can be between two rings at the distal or proximal portion of the stent.

Response to Arguments

2. Applicant's arguments filed July 14, 2008, directed to the Vardi et al. (6,325,826) references applied in the previous Office Action are acknowledged and deemed persuasive, thus, those rejections have been withdrawn.

3. Applicant's arguments regarding the Callol et al. (2002/0183763) reference applied in the previous Office Action are acknowledged and deemed not persuasive. The claims, as amended, have been carefully considered but they deemed not allowable in view of the following rejection based on the same prior art of record as follows.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 14, 15, 20-22, and 36-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8-18 of copending Application No. 11/744,812. Although the conflicting claims are not identical, they are not patentably distinct from each other because the slight difference in the wording of the claims involves an identical structure.

The claim limitations of claim 14 are found in the combination of claims 1 and 8 of Application 11/744,812.

With respect to claims 15 and 20-22, these limitations are found in claims 15-18 of the Application 11/744,812.

With respect to claims 36-46, these limitations are found in claims 8-18 of the Application 11/744,812.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 14, 15, 20-22, 45, and 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8-18 of copending Application No. 11/744,802. Although the conflicting claims are not identical, they are not patentably distinct from each other because the slight difference in the wording of the claims involves an identical structure.

The claim limitations of claim 14 are found in the combination of claims 1 and 10 of

Application 11/744,802.

With respect to claims 15 and 20-22, these limitations are found in claims 17-20 of the Application 11/744,802.

With respect to claims 45 and 46, these limitations are found in claims 19 and 20 of the Application 11/744,802, respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 14-18, 23, 24, 36, 43, 44, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Jayaraman (5,755,781).

Jayaraman discloses the following claimed limitations:

Claim 14: A prosthesis (20, 70) for placement at an opening from a main body lumen to a branch body lumen, the prosthesis comprising: a radially expansible support (see figure below), the support configured to be deployed in at least a portion of the branch body lumen; at least two elongate, flexible fronds (combination of 27 and 29 in Fig. 4, 71 in Fig. 9) each having a first end, a second end and a length in between (Fig. 4 and 9), the fronds extending from an end of the support and configured to be positioned across the Os and into the main body lumen (see figure below); and at least one circumferential link (see figure below) connected to the second ends of the fronds (see figure below), the circumferential link spaced axially apart from the support by the fronds (see figure below); the elongate, flexible fronds, the support and the circumferential link defining a unitary body as deployed (Fig. 4, 9, and 28), having elongate side wall openings in between adjacent fronds (the gaps between each frond seen in the figure below) for facilitating crossing of a main vessel stent therethrough when the support is positioned in the branch body lumen and the circumferential link is positioned in the main body lumen.

Regarding the last statement, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

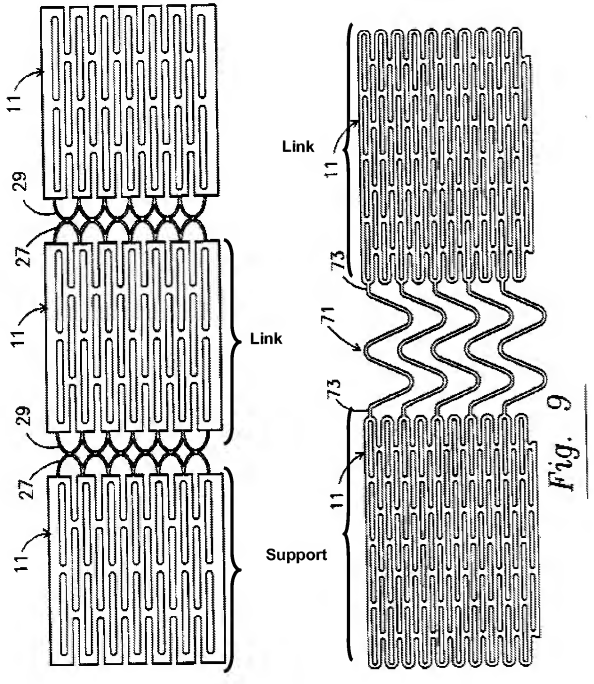

Fig. 9

Claim 15: The circumferential link comprises an undulating pattern having at least three apexes (the link contains an undulating pattern with more than three apexes as seen in the figure above).

Claim 16: Comprising three fronds (Fig. 4 and 9).

Claim 17: At least one frond comprises a helical configuration (Fig. 9 where the fronds have a spiral/helical shape).

Claim 18: A plurality of helical fronds (Fig. 9).

Claim 23: The prosthesis comprising an endothelial cell ingrowth surface (Fig. 4 and 9). The surface is capable of promoting cell ingrowth.

Claim 24: The prosthesis comprising a non thrombogenic surface (Col. 6 Lines 35-37).

Claim 36: At least one frond comprises a plurality of parallel, undulating filaments (Fig. 4).

Claim 43: That the circumferential link comprises a single transverse filament (see figure above where the link is made from a single material that is laser cut (Col. 4 Lines 10-20).

Claim 44: Comprising a transition section (73) between the support and the fronds (see figure above).

Claim 47: That the prosthesis includes a drug incorporated into a polymer matrix (Col. 4 Lines 30-32).

9. Claims 14-16, 21, 22, 36-41, 43, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Callol et al. (2002/0183763).

Callol discloses the following claimed limitations:

Claim 14: A prosthesis for placement at an opening from a main body lumen to a branch body lumen, the prosthesis comprising: a radially expansible support (26), the support configured to be deployed in at least a portion of the branch body lumen ([0140] last sentence); at least two elongate, flexible frond (39 see the figure below, where each frond is each portion that extends from the support 26 to the peak) each having a first end (the portion connected to the support (26)), a second end (the end of the peaks which connects to portion (29)), and a length between (see figure below), the fronds extending from an end of the support (26) (see figure below) and configured to be positioned across the Os and into the main body lumen (Fig. 40-41); and at least one circumferential link (proximal portion of 29) connected to the second end of the fronds (39), the circumferential link spaced axially apart from the support by the fronds (see figure below); the elongate, flexible fronds, the support and the circumferential link defining a unitary body as deployed (see figure below), having elongate side wall openings in between adjacent fronds (the gaps between each frond seen in the figure below) for facilitating crossing of a main vessel stent therethrough when the support is positioned in the branch body lumen and the circumferential link is positioned in the main body lumen (Fig. 40-41).

Regarding the last statement, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

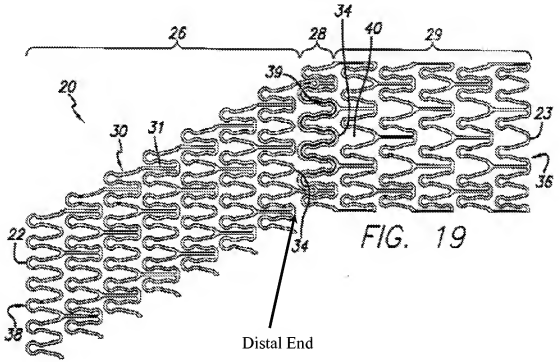

FIG. 19

Claim 15: That the circumferential link comprises an undulating pattern having at least three apexes (the proximal end of the part 29 contains an undulating pattern with more than three apexes as seen in the figure above).

Claim 16: That there is three fronds (39 see the figure above, where each frond is each portion that extends from the support 26 to the peak).

Claim 21: That the circumferential link is radiopaque ([0148] first sentence). The link is made from a ring (30) and strut (31) which can have variable thicknesses that provide higher radiopacity therefore they are radiopaque.

Claim 22: That the circumferential link has a greater radiopacity than the frond. The radiopacity of the link as disclosed in paragraph [0152] varies depending on the

thickness of the ring (30) and the strut (31) therefore the link is capable of having higher radiopacity than the frond. Furthermore, the frond (39) is not radiopaque which indicates that the link will have higher radiopacity than the frond.

Claim 36: At least one frond comprises a plurality of parallel, undulating filaments (see figure above).

Claim 37: That at least a portion of the radially expansible support (26) comprises a drug coating ([0150] Lines 1-2), and at least a portion of the fronds (39) and the circumferential link (29) are without a drug coating (Claim 20). It is disclosed that the device can be coated completely or only portions which indicates that the fronds and link are not coated.

Claim 38: That the drug coating is configured to produce a controlled drug release rate ([0150] Lines 9-11).

Claim 39: That the drug is one of an anti-cell prolifertive ([0150] Lines 18-19), anti cell migration, anti-neo plastic, anti inflammatory drug ([0150]).

Claim 40: That the drug is configured to reduce restensosis ([0150] Lines 1-4).

Claim 41: That the drug coating includes a first coating and a second coating ([0150] Lines 4-11).

Claim 43: That the circumferential link comprises a single transverse filament (the circumferential link is the proximal end of part 29 which is a single loop that is transverse to the longitudinal axis of the device) (Fig. 19).

Claim 44: A transition section (34) between the support and the fronds (Fig. 19).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaraman (5,755,781) in view of Summers et al. (5,342,387).

Jayaraman teaches all the claimed limitations discussed above including that the device contains a coating (Col. 4 Lines 23-25) however, Jayaraman does not disclose a lubricous coating.

Summer discloses that at least a portion of the at least one frond comprises a lubricous coating (Col. 4 Lines 27-30). The surface of the stent (this includes the fronds) is coated with a gel coating which causes the surface to be smooth (Col. 4 Lines 36-40).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Jayaraman with a lubricous coating in view of the teachings of Summer, in order to have a smooth surface to avoid abrasions on the vessel wall.

12. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaraman (5,755,781).

Jayaraman discloses the claimed invention except for the axial length of the fronds being at least 8mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the length of the fronds at least

8mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

13. Claims 42, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callol et al. (2002/0183763) in view of Jang (2004/0106985).

Claim 42:

Callol teaches all the claimed limitations discussed above however, Callol does not disclose that the first coating is configured to produce a first drug release rate and the second coating is configured to produce a second drug release rate.

Jang discloses that the first coating is configured to produce a first drug release rate and the second coating is configured to produce a second drug release rate ([0351]).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Callol with different release rates for the drug coatings in view of the teachings of Jang, in order to control the amount of drug that is released as well as to better enable safe encapsulation of the implanted stent.

Claims 50 and 51:

Callol teaches all the claimed limitations discussed above however, Callol does not disclose that the prosthesis includes one or more reservoirs configured to be loaded with one or more drugs.

Jang discloses that the prosthesis includes one or more reservoirs (27) configured to be loaded with one or more drugs ([0352] first sentence).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Callol with reservoirs for loading one or more drugs in view of the teachings of Jang, in order to facilitate the retention and delivery of the drugs.

14. Claims 47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callol et al. (2002/0183763) in view of Rudakov et al. (6,451,050).

Claim 47:

Callol teaches all the claimed limitations discussed above however, Callol does not disclose that the prosthesis includes a drug incorporated into a polymer matrix.

Rudakov discloses that the prosthesis includes a drug incorporated into a polymer matrix (Col. 4 Lines 41-43).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Callol with drug incorporated to a polymer matrix in view of the teachings of Rudakov, in order to incorporate the drug into the stent which is well known in the art.

Claim 49: Callol discloses that the polymer includes a base layer and a top layer (a first and second coating), the drug being incorporated into at least one of the top layer and the base layer ([0150] Lines 4-11)

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/Julian W. Woo/
Primary Examiner, Art Unit 3773

September 29, 2008